

CLAIMS:

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1. Water soluble particles of less than 50 μm comprising a coprecipitant core with a dehydrated biological macromolecule coated thereon.
- 5 2. Water soluble particles according to claim 1 wherein the coprecipitant is partially or substantially crystalline.
- 10 3. Water soluble particles according to claim 1 wherein the dehydrated biological macromolecule is selected from peptides, polypeptides, proteins and nucleic acid.
- 15 4. Water soluble particles according to claim 1 having a diameter less than 10 μm .
- 20 5. Water soluble particles according to claim 1 wherein the coprecipitant is selected from inorganic salts, sugars, polysaccharides, carbohydrates, polyols, and derivatives thereof, *for example*, trehalose, with a molecular weight of less than 10,000 Da; amino-acids *such as glycine and arginine*; acid-base buffers; zwitterionic compounds; organic salts; compounds containing multiple basic groups; compounds containing multiple acidic groups; 25 bile salts;

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water soluble dyes;
polar or ionic polymers; and
polar or ionic dendrimers.

5 6. A method of preparing water soluble particles comprising a coprecipitant core with a dehydrated biological macromolecule coated thereon comprising the steps of:

- preparing an aqueous solution comprising a coprecipitant and a biological macromolecule;
- rapidly admixing the biological macromolecule/coprecipitant solution with

10 an excess of a water miscible organic solvent such that the coprecipitant and bioactive molecule immediately coprecipitate from solution forming said particles; and

- isolating said particles from the organic solvent.

15 7. The method according to claim 6 wherein the aqueous solution comprising the coprecipitant and the biological macromolecule is prepared by dissolving the coprecipitant in an aqueous solution comprising the biological macromolecule.

20 8. The method according to either of claims 6 or 7 wherein the biological macromolecule/coprecipitant solution is added to the water miscible organic solvent.

9. The method according to claim 6 wherein the coprecipitant:biological macromolecule molar ratio is greater than 50.

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10. The method according to claim 6 wherein the coprecipitant is selected from
inorganic salts;
sugars, polysaccharides, carbohydrates, polyols, and derivatives thereof, for example
5 trehalose, with a molecular weight of less than 10,000 Da;
amino-acids;
acid-base buffers;
zwitterionic compounds;
organic salts;
10 compounds containing multiple basic groups;
compounds containing multiple acidic groups;
bile salts;
water soluble dyes;
polar or ionic polymers; and
15 polar or ionic dendrimers.

11. The method according to claim 6 wherein the organic solvent is selected from methanol, ethanol, propanol, acetonitrile tetrahydrofuran and acetone.

20 12. Particles obtainable by the process according to claim 6.

13. A pharmaceutical formulation comprising particles according to claims 1 or 12 and a suitable carrier therefore.

14. A medical device comprising particles according to claims 1 or 12
associated therewith.

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15. Particles according to claims 1 or 12 for use in therapy.
16. A biocatalyst preparation comprising particles according to claims 1 or 12
associated therewith.

17. A cleansing agent comprising enzyme coated particles according to claims
10 1 or 12.

18. A protective or antifouling agent comprising particles according to claims
1 or 12 in association with paint, varnish, coatings or films.

15 19. Films, polymers, inks, coatings, electrodes and optical materials for
diagnostic kits or biosensor applications, comprising particles according to claims 1 or
12.

20. A method for studying molecular recognition, molecular binding,
20 molecular imprinting or inhibitor binding in non-aqueous media, comprising using
particles according to claims 1 or 12.

21. A method for studying macromolecule structure and/or organisation by
scanning probe microscopy, comprising using particles according to claims 1 or 12.

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22. A method of isolating a biological macromolecule from an aqueous solution, comprising the steps of:

a) preparing an aqueous solution comprising a mixture of a coprecipitant and biological macromolecule to be isolated; and
5 b) admixing the biological macromolecule/coprecipitant solution with an excess of a water miscible organic solvent such that the coprecipitant and biological macromolecule immediately coprecipitate from solution, with rapid simultaneous dehydration of the biological macromolecule.

10 ✓ 23. Water soluble particles of less than 50 µm comprising a coprecipitant core with a dehydrated biological macromolecule coated thereon obtainable by:

a) preparing an aqueous solution comprising a coprecipitant and biological macromolecule; and
15 b) admixing the biological macromolecule/coprecipitant solution with an excess of a water miscible organic solvent such that the coprecipitant and biological macromolecule immediately coprecipitate from solution forming said particles; and
c) isolating said particles from the organic solvent.

✓ 24. Biological macromolecule coated micro-crystals comprising a coprecipitant core with a dehydrated biological macromolecule coated thereon wherein the coprecipitant is selected from inorganic salts, sugars, polysaccharides, carbohydrates, polyols, and derivatives thereof, for example trehalose, with a molecular weight of less than 10,000 Da; amino-acids such as glycine and arginine;
25 acid-base buffers;

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zwitterionic compounds;
organic salts;
compounds containing multiple basic groups;
compounds containing multiple acidic groups;
5 bile salts;
water soluble dyes;
polar or ionic polymers; and
polar or ionic dendrimers.

10 25. A pharmaceutical formulation comprising biological macromolecule coated micro-crystals comprising a coprecipitant cover with a dehydrated pharmaceutically active biological macromolecule coated thereon wherein the coprecipitant is selected from inorganic salts, sugars, polysaccharides, carbohydrates, polyols, and derivatives thereof, for example trehalose, with a molecular weight of less than 10,000 Da; amino-acids such as glycine and arginine; acid-base buffers; zwitterionic compounds; organic salts; 20 compounds containing multiple basic groups; compounds containing multiple acidic groups; bile salts; water soluble dyes; polar or ionic polymers; and 25 polar or ionic dendrimers; and a suitable carrier therefore.

26. An inhalable pharmaceutical formulation comprising biological macromolecule coated micro-crystals comprising a coprecipitant core with a dehydrated pharmaceutically active biological macromolecule coated thereon.

5 27. Water soluble particles of less than 50 µm comprising a coprecipitant partially, substantially or crystalline core with a dehydrated biological macromolecule coated thereon.

10 28. Water soluble particles comprising a coprecipitant core with a dehydrated biological macromolecule coated thereon, wherein the coprecipitant is selected from ionic salts, amino acids, zwitterionic compounds, organic salts, sugars and polysaccharides of a molecular weight of less than 10,000 Da.

15 29. Water soluble particles according to claim 28 wherein the coprecipitant has a molecular weight of less than 1,000 Da.

20 30. Water soluble particles comprising a coprecipitant core coated with a dehydrated biological macromolecule wherein the coprecipitant has a melting point at atmospheric pressure greater than 95° C.

31. A liquid suspension comprising water soluble particles comprising a coprecipitant core coated with a biological macromolecule.

25 32. A method of purifying a biological macromolecule from additives or impurities comprising:

- a) dissolving a coprecipitant in an aqueous solution comprising the biological macromolecule and additive or impurity;
- b) admixing the biological macromolecule/coprecipitant solution with an excess of a water miscible organic solvent or solvents, in which the additive or impurity

5 is soluble, such that the coprecipitant and biological macromolecule immediately coprecipitate from solution forming a biological macromolecule coated particle comprising a core of coprecipitant;

- c) rinsing said particles with fresh water-miscible organic solvent; and
- d) isolating said particles.

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